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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,730	02/10/2000	Merry R. Sherman	MVIEW.0050A	4303

7590 06/18/2003

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/18/2003 27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/501,730	SHERMAN ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-28 and 33-41* is/are pending in the application.

4a) Of the above claim(s) *11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-28 and 33* is/are rejected.

7)☐ Claim(s) *34-37,40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on April 1, 2003, amending claims 1 and 33 and entering claims 38-41, has been entered.

Claims 1-9, 11-28 and 33-41 are pending.

Election/Restrictions

Claims 11-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Information Disclosure Statement

The translated references of DD 279 486 A1 and JP 09154581 have been considered. A copy of the form-1449 is attached to this action.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 17-28 and 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al.

Williams et al. (U.S. Patent No. 6,576,235 – form PTO-892) teach a uricase containing 2% or less non-tetrameric aggregated uricase (Column 12, lines 44-65). Williams et al. also teach a porcine, bovine or ovine liver uricase, a chimeric uricase, a PKS uricase, and variants of mammalian uricases (claims 1-17). Williams et al. also teach various PEG-uricase (claims 18-27 and Column 11). Therefore, the teachings of Williams et al. anticipates claims 1-9, 17-28 and 33-41.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 17-28 and 33-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,576,235. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter,

as follows: uricase containing less than 2% of non-tetrameric aggregated uricase, various mutants of uricase and PEG-uricase.

Response to Arguments

Applicant's arguments filed on April 1, 2003 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Aleman et al.

Applicants argue that Aleman et al. is silent on the issue of whether the uricase is free of aggregates larger than tetramers. Some uricases function as tetramers and therefore the aggregates Aleman et al. is trying to alleviate are aggregates larger than tetramers. Applicants argue that solutions of uricase that contain aggregates larger than octamers can appear to be visibly clear. Applicants offer several examples of there clear solutions containing uricase has about 14-26% of their total protein in the form of aggregates larger than octamers. Amended claim 1 is drawn to an uricase wherein about 20% of the uricase is in the tetrameric or octameric aggregated uricase and wherein about 80% is in a non-tetrameric or octameric aggregated uricase, a significant amount. Therefore, the uricase of Aleman et al. can contain less than 20% of its total protein in the form of aggregates larger than octamers.

Also, although the reference of Aleman et al. does not explicitly teach the exact degree of the presence of large aggregates, one of ordinary skill in the art would recognize that the uricase of Aleman et al. has less than 80% of aggregates larger than tetramers since Poloxamer 188 and Polysorbate 80 aids in reducing the degree of aggregation of urate oxidase in solution by as much as three fold, resulting in a stable pharmaceutical composition (Figure 1, Composition 2 and Column 1, lines 5-10).

Therefore, the teachings of Aleman et al. anticipate claims 1, 4, 6 and 33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aleman et al. in view of Wu et al.

Applicants' arguments and the examiner's answer are discussed above.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make the composition of Aleman et al. using the uricase of Wu et al. The motivation is to stabilize a composition comprising a mammalian

uricase for use as a therapeutic in man. One of ordinary skill in the art would have had a reasonable expectation of success since Aleman et al. successfully stabilized a composition comprising an uricase.

Claims 1-7, 9 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aleman et al. in view of Wu et al.

Applicants' arguments and the examiner's answer are discussed above.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a chimeric uricase by replacing Tyr 97 of the baboon uricase with Try97 of the porcine uricase and stabilize the protein by the method taught by Aleman et al.. One would be motivated to replace a residue with a conserved residue because conserved amino acids very often impart the characteristic property of an enzyme. One of ordinary skill in the art would have had a reasonable expectation of success since site specific mutations are routinely performed in the art.

Claims 1 and 17-25 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aleman et al. in view of Delgado et al.

Applicants' arguments and the examiner's answer are discussed above.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make the composition of Aleman et al. using the conjugate of Delgado et al. The motivation is to further stabilize a composition

comprising the protein for use as a therapeutic in man. One of ordinary skill in the art would have had a reasonable expectation of success since Aleman et al. and Delgano et al. successfully stabilized a composition comprising an uricase.

Allowable Subject Matter

Claims 34-37 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

June 13, 2003

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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